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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD-2015-HA-0062]

RIN: 0720-AB64

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/

TRICARE: Refills of Maintenance Medications Through Military Treatment Facility

Pharmacies or National Mail Order Pharmacy Program

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: This final rule implements section 702 (c) of the Carl Levin and Howard P.

“Buck” McKeon National Defense Authorization Act for Fiscal Year 2015 which states that

beginning October 1, 2015, the pharmacy benefits program shall require eligible covered

beneficiaries generally to refill non-generic prescription maintenance medications through

military treatment facility pharmacies or the national mail-order pharmacy program. An interim

final rule is in effect. Section 702(c) of the National Defense Authorization Act for Fiscal Year

2015 also terminates the TRICARE For Life Pilot Program on September 30, 2015. The

TRICARE For Life Pilot Program described in section 716(f) of the National Defense

Authorization Act for Fiscal Year 2013, was a pilot program which began in March 2014

requiring TRICARE For Life beneficiaries to refill non-generic prescription maintenance

medications through military treatment facility pharmacies or the national mail-order pharmacy

program. TRICARE for Life beneficiaries are those enrolled in the Medicare wraparound

coverage option of the TRICARE program. This rule includes procedures to assist beneficiaries in transferring covered prescriptions to the mail order pharmacy program.

DATES: *Effective Date:* This rule is effective [insert date 65 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. George Jones, Jr., Chief, Pharmacy Operations Division, Defense Health Agency, telephone 703-681-2890.

SUPPLEMENTARY INFORMATION:

A. EXECUTIVE SUMMARY

1. Purpose.

This final rule implements Section 702 (c) of the Carl Levin and Howard P. “Buck” McKeon National Defense Authorization Act for Fiscal Year 2015 which states that beginning October 1, 2015, the pharmacy benefits program shall require eligible covered beneficiaries generally to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail-order pharmacy program. Eligible covered beneficiaries are defined in sections 1072 (5) and 1086 of title 10, United States Code.

2. Summary of the major provisions of the final rule.

TRICARE beneficiaries are generally required to obtain all prescription refills for select non-generic maintenance medications from the TRICARE mail order program (where beneficiary copayments are much lower than in retail pharmacies) or military treatment facilities (where there are no copayments). Covered maintenance medications are those prescribed for chronic, long-term conditions that are taken on a regular, recurring basis, but do not include medications to treat acute conditions. TRICARE will follow best commercial practices, including that beneficiaries will be notified of the new rules and mechanisms to allow them to

receive adequate medication during their transition to mail for their refills. The statute and rule authorize a waiver of the mail order requirement based on patient needs and other appropriate circumstances.

3. Costs and benefits.

The effect of the statutory requirement, implemented by this rule, is to shift a volume of prescriptions from retail pharmacies to the mail order pharmacy program. This will produce savings to the Department of approximately \$81million per year and savings to beneficiaries of approximately \$20 million per year in reduced copayments.

B. BACKGROUND.

In Fiscal Year 2014, 61 million prescriptions were filled for TRICARE beneficiaries through the TRICARE retail pharmacy benefit at a net cost of \$5.1 billion to the government. On average, the government pays 32% less for brand name maintenance medication prescriptions filled in the mail order program or military treatment facility pharmacies than through the retail program. Not all prescriptions filled through the retail program are maintenance/chronic medications. However, there is potential for significant savings to the government by shifting a portion of TRICARE prescription refills to the mail order program or military treatment facility pharmacies. In addition, there will be significant savings to TRICARE beneficiaries who will receive up to a 90 day refill at no charge for generics in the mail order program compared to \$10 copay for up to a 30 day in retail. The savings is even greater for brand-name prescriptions: \$20 for up to 90 days in mail versus \$24 for up to 30 days in retail, meaning that for a 90-day supply the copayment comparison is \$20 in mail to \$72 in retail. The non-formulary copayment amount is \$49 for up to 90 days in mail non-formulary drugs are generally not available in retail.

C. SUMMARY OF THE FINAL RULE.

The final rule revises paragraph (r) to 32 CFR 199.21. This paragraph (r) establishes rules for the new program of refills of maintenance medications for TRICARE through the mail order pharmacy program. Paragraph (r)(1) requires that for covered non-generic maintenance medications, TRICARE beneficiaries are generally required to obtain their prescription refills through the national mail order pharmacy program or through military treatment facility pharmacies. TRICARE beneficiaries are defined in sections 1072(5) and 1086 of title 10, United States Code, including those enrolled in the Medicare wraparound coverage option of the TRICARE program.

Paragraph (r)(2) provides that the Director, Defense Health Agency will establish, maintain, and periodically revise and update a list of covered maintenance medications, which will be accessible through the TRICARE Pharmacy Program Web Site and by telephone through the TRICARE Pharmacy Program Service Center. Each medication included on the list will be a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis. It will be clinically appropriate and cost effective to dispense the medication from the mail order pharmacy. It will be available for an initial filling of a 30-day or less supply through retail pharmacies, and will be generally available at military treatment facility pharmacies for initial fill and refills. It will be available for refill through the national mail-order pharmacy.

Paragraph (r)(3) provides that a refill is a subsequent filling of an original prescription under the same prescription number or other authorization as the original prescription, or a new original prescription issued at or near the end date of an earlier prescription for the same medication for the same patient.

Paragraph (r)(4) provides that a waiver of the general requirement to obtain maintenance medication prescription refills from the mail order pharmacy or military treatment facility pharmacy will be granted in several circumstances. There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstance, for example, for nursing home residents. This waiver is obtained through an administrative override request to the TRICARE pharmacy benefits manager under procedures established by the Director, Defense Health Agency.

Paragraph (r)(5) establishes procedures for the effective operation of the program. The Department will implement the program by utilizing best commercial practices to the extent practicable. An effective communication plan that includes efforts to educate beneficiaries in order to optimize participation and satisfaction will be implemented. Beneficiaries with active prescriptions for a medication on the maintenance medication list will be notified that their medication is covered under the program. Beneficiaries will be advised that they may receive up to two 30 day fills at retail while they transition their prescription to the mail order program. The beneficiary will be contacted after each of these two fills reminding the beneficiary that the prescription must be transferred to mail. Requests for a third fill at retail will be blocked and the beneficiary advised to call the pharmacy benefits manager (PBM) for assistance. The PBM will provide a toll free number to assist beneficiaries in transferring their prescriptions from retail to the mail order program. With the beneficiary's permission, the PBM will contact the physician or other health care provider who prescribed the medication to assist in transferring the prescription to the mail order program. In any case in which a beneficiary is required to obtain a maintenance medication prescription refill from the national mail-order pharmacy program and

attempts instead to refill such medications at a retail pharmacy, the PBM will also maintain the toll free number to assist the beneficiary. This assistance may include information on how to request a waiver or in taking any other appropriate action to meet the beneficiary's needs and to implement the program. The PBM will ensure that a pharmacist is available at all times through the toll-free telephone number to answer beneficiary questions or provide other appropriate assistance.

Paragraph (r)(6) provides that the program will remain in effect indefinitely with any adjustments or modifications required by law.

D. SUMMARY OF AND RESPONSE TO PUBLIC COMMENTS

The interim final rule was published in the Federal Register (80 FR 46796) August 6, 2015, for a 60-day comment period. We received six comments on the interim final rule; four comments from individuals and two comments from professional associations. We appreciate these comments, which are summarized here, along with DoD's response.

Comment: One comment expressed concern regarding the possibilities of delays in the mail causing the patient to miss a day or more of their medication.

Response: The provisions of the TRICARE pharmacy contract permit beneficiaries to refill medications well in advance of the refill due date to allow for adequate shipping time.

Additionally, this final rule provides for a case-by-case waiver to permit prescription maintenance medication refill at a retail pharmacy when necessary due to personal need or hardship, emergency, or special circumstance.

Comment: One commenter objected to the lack of clear communication from ESI by stating that conflicting messages are often given to a beneficiary who calls with a question, i.e. your medications has been shipped, your medication has not been shipped, etc. The same individual

suggests that Prior Approvals for brand name products often get deleted from the system requiring the beneficiary to repeat the PA process.

Response: DoD acknowledges the commenter's concerns regarding contractor communication and Prior Approvals being deleted from the system, both of which are contract specific issues, and not part of the regulatory language. It should be noted that Prior Approvals may be time limited depending on the medication. DoD will consider the feedback for incorporation into future contractor customer service performance requirements.

Comment: One commenter inquired why Active Duty personnel are not required to participate in this mandatory program which appears to be targeting retirees. In addition, the individual suggested a blanket waiver be administered for retirees who live in remote areas with very limited MTF pharmacy access. A final concern asked if MTF staffing has been increased to accommodate the potential influx of retirees.

Response: This final rule conforms with the current statutory requirement of Section 702 in the fiscal year (FY) 2015 National Defense Authorization Act, requiring eligible covered beneficiaries generally to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail order program. Eligible covered beneficiaries are defined in Title 10, Section 1072 (5) and does not include Active Duty service members. The statute and the rule designate military treatment facility (MTF) pharmacies or the mail order pharmacy program as the two options available to beneficiaries for obtaining refills of non-generic prescription maintenance medications. For those beneficiaries who live in remote areas with limited MTF access, the mail order pharmacy program is an ideal option saving both time and copayment expenses. Our experience and data from the TRICARE FOR LIFE maintenance medication pilot showed that there was sufficient capacity to accommodate the

change, both at mail order and in the MTFs. Our data show that the overall impact on the MTF workload was very minimal, while majority of the prescriptions went to mail order. The movement of brand maintenance medications from retail to mail order actually saves beneficiaries out-of-pocket expenses in the form of reduced copays and up to a 90 day supply for less than the 30 day copay at retail. This provides a win-win scenario for the beneficiary and the government.

Comment: One commenter cited anecdotal evidence in Alabama that resulted in emergency room visits from ingesting mail order prescriptions that had been exposed to excessive heat. The commenter expressed concerns about proper temperature control of medications shipped through the mail and suggests the rule include a requirement that all medications must be kept within the FDA's recommended range of 59-86 degrees.

Response: The pharmacy contractor reviews all medications dispensed through the mail order pharmacy for unique shipping requirements, based on information from the manufacturer. For medications that are temperature-sensitive, special shipping procedures are followed. The temperature-sensitive medications are mailed via expedited overnight shipping or 2nd day air, at no cost to the beneficiary. Before certain medications are delivered, a scheduling call is made to the beneficiary to arrange a delivery time and date.

Comment: A professional association commented with a number of concerns: beneficiaries should continue to have choice, flexibility, and easy access to prescription medications; unnecessary waste resulting from auto-ship policies and the suggestion to implement policies to ensure mail order refills are approved and needed; DoD should conduct and publicize a beneficiary satisfaction survey at the end of each year; beneficiaries should be properly informed

about the options to seek a waiver and clear instructions on how to obtain one; DoD should develop and make available a complete list of acute care meds.

Response: This final rule conforms with the current statutory requirement of Section 702 in the FY 2015 NDAA requiring eligible covered beneficiaries generally to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail order program. DoD believes it is being implemented successfully and without adverse effects on beneficiaries. Non-generic prescription maintenance medications subject to the program are listed at www.health.mil/selectdruglist. DoD has determined it unnecessary to have an additional list to specify acute care medications that are not subject to the program. DoD continues to monitor beneficiary satisfaction of the TRICARE pharmacy program.

Comment: A professional association commented with the following concerns: The rule should clearly indicate that covered maintenance medications include non-generic only; beneficiaries should have to consent to getting a refill rather than automatic shipping; mandatory mail results in a silo approach where the patient gets prescriptions from multiple sources resulting the lack of coordinated care; community pharmacists are often the sole source for medication and patient education and can only judge the patient's understanding by in-person interactions; communications to beneficiaries regarding waivers should include complete information on how to obtain a waiver.

Response: Section 199.21(r)(1) has been amended to insert "non-generic" prior to "covered medications". Contractor requirements are not part of the regulatory language. In order to participate in the mail order auto-ship program, beneficiaries must consent to auto-ship enrollment but are not required to do so. Beneficiaries enrolled in the auto-ship program are notified prior to medication shipment.

E. REGULATORY PROCEDURES.

Executive Order 12866, “Regulatory Planning and Review”

Executive Order (EO) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined primarily as one that would result in an effect of \$100 million or more in any one year. The DoD has examined the economic and policy implications of this final rule and based on the resulting analysis, the Office of Management and Budget has concluded that this is an economically significant regulatory action under the Executive Order. The program rule will produce savings to the Department of approximately \$81M per year and savings to beneficiaries of approximately \$20 million per year in reduced copayments. This rule results in a shift of workload from retail pharmacies to the mail order program. This workload shift is estimated to result in a net impact to retail pharmacy margins nationwide of \$15.6 million in FY17 dollars. This rule has been designated an economically significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

Congressional Review Act, 5 U.S.C. 801, et seq.

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of \$100 million or more or have certain other impacts. This final rule is not a major rule under the Congressional Review Act.

Section 202, Pub. L. 104-4, “Unfunded Mandates Reform Act”

This rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more (adjusted for inflation) in any one year.

Public Law 96-354, “Regulatory Flexibility Act” (5 U.S.C. 601)

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This final rule does not have a significant impact on a substantial number of small entities.

Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

This final rule contains no new information collection requirements subject to the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3511).

Executive Order 13132, “Federalism”

This final rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on the States; the relationship between the National Government and the States; or the distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 199

Administrative practice and procedure, Claims, Dental health, Fraud, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199--[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.21 is amended by revising paragraph (r) to read as follows:

§ 199.21 TRICARE Pharmacy Benefits Program.

* * * * *

(r) Refills of maintenance medications for eligible covered beneficiaries through the mail order pharmacy program-(1) In general Consistent with section 702 of the National Defense Authorization Act for Fiscal Year 2015, this paragraph requires that for non-generic covered maintenance medications, beneficiaries are generally required to obtain their prescription through the national mail-order pharmacy program or through military treatment facility pharmacies. For purposes of this paragraph, eligible covered beneficiaries are those defined under sections 1072 and 1086 of title 10, United States Code.

(2) Medications covered. The Director, DHA, will establish, maintain, and periodically revise and update a list of non-generic covered maintenance medications subject to the requirement of paragraph (r)(1) of this section. The current list will be accessible through the TRICARE Pharmacy Program Internet Web site and by telephone through the TRICARE Pharmacy Program Service Center. Each medication included on the list will meet the following requirements:

(i) It will be a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis

(ii) It will be clinically appropriate to dispense the medication from the mail order pharmacy.

(iii) It will be cost effective to dispense the medication from the mail order pharmacy.

(iv) It will be available for an initial filling of a 30-day or less supply through retail pharmacies.

(v) It will be generally available at military treatment facility pharmacies for initial fill and refills.

(vi) It will be available for refill through the national mail-order pharmacy program.

(3) Refills covered. For purposes of the program under paragraph (r)(1) of this section, a refill is:

(i) A subsequent filling of an original prescription under the same prescription number or other authorization as the original prescription; or

(ii) A new original prescription issued at or near the end date of an earlier prescription for the same medication for the same patient.

(4) Waiver of requirement. A waiver of the general requirement to obtain maintenance medication prescription refills from the mail order pharmacy or military treatment facility pharmacy will be granted in the following circumstances:

(i) There is a blanket waiver for prescription medications that are for acute care needs.

(ii) There is a blanket waiver for prescriptions covered by other health insurance.

(iii) There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstance. This waiver is obtained through an administrative override request to the TRICARE pharmacy benefits manager under procedures established by the Director, DHA.

(5) Procedures. Under the program established by paragraph (r)(1) of this section, the Director, DHA will establish procedures for the effective operation of the program. Among these procedures are the following:

(i) The Department will implement the program by utilizing best commercial practices to the extent practicable.

(ii) An effective communication plan that includes efforts to educate beneficiaries in order to optimize participation and satisfaction will be implemented.

(iii) Beneficiaries with active retail prescriptions for a medication on the maintenance medication list will be notified that their medication is included under the program. Beneficiaries will be advised that they may receive two 30 day fill at retail while they transition their prescription to the mail order program.

(iv) Requests for a third fill at retail will result in 100% patient cost shares and will be blocked from any TRICARE payments and the beneficiary advised to call the pharmacy benefits manager (PBM) for assistance.

(v) The PBM will provide a toll free number to assist beneficiaries in transferring their prescriptions from retail to the mail order program. With the beneficiary's permission, the PBM will contact the physician or other health care provider who prescribed the medication to assist in transferring the prescription to the mail order program.

(vi) In any case in which a beneficiary required under paragraph (r) of this section to obtain a maintenance medication prescription refill from national mail order pharmacy program and attempts instead to refill such medications at a retail pharmacy, the PBM will also maintain the toll free number to assist the beneficiary. This assistance may include information on how to request a waiver, consistent with paragraph (r)(4)(iii) of this section, or in taking any other appropriate action to meet the beneficiary's needs and to implement the program.

(vii) The PBM will ensure that a pharmacist is available at all times through the toll-free telephone number to answer beneficiary questions or provide other appropriate assistance.

(6) This program will remain in effect indefinitely with any adjustments or modifications required by law.

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Dated: October 28, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

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